Food and Drug Administration, HHS

- (2) Indications for use. For increased rate of weight gain and improved feed efficiency.
- (3) Limitations. For heifers weighing 400 pounds or more; for subcutaneous ear implantation, one dose per animal; not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[69 FR 68252, Nov. 24, 2004]

§ 522.850 Estradiol valerate and norgestomet in combination.

- (a) *Specifications*. The product is a two-component drug consisting of the following:
- (1) An implant containing 6.0 milligrams of norgestomet.
- (2) An injectable solution (sesame oil) containing 3.0 milligrams of norgestomet and 5.0 milligrams of estradiol valerate per 2 milliliters.
- (b) Sponsor. See 050604 in \$510.600(c) of this chapter.
- (c) Conditions of use—(1) Amount. One implant and 2 milliliters of injection at time of implantation.
- (2) Indications for use. For synchronization of estrus/ovulation in cycling beef cattle and non-lactating dairy heifers.
- (3)Limitations.implant Insert subcutaneously in the ear only; then immediately inject solution intramuscularly only. Counting the day of implantation as day 1, remove the implant on day 10. Collect all implants as they are removed and burn them. While animals are restrained for artificial insemination, avoid other treatments such as vaccinations, dipping, pour-on grub and louse prevention, spraying, etc. When inseminating without estrus detection, the entire treated group should be started at 48 hours after the last implant has been removed and should be completed within 6 hours. Where estrus detection is preferred, insemination should be approximately 12 hours after first detection of estrus. Those that do not conceive can be re-bred when they return to estrus approximately 17 to 25 days after implant removal. Do not use in

cows producing milk for human consumption.

 $[47\ {\rm FR}\ 55477,\ {\rm Dec.}\ 10,\ 1982,\ {\rm as}\ {\rm amended}\ {\rm at}\ 48$ FR 49656, Oct. 27, 1983; 51 FR 33592, Sept. 22, 1986; 54 FR 1165, Jan. 12, 1989]

§ 522.863 Ethylisobutrazine hydrochloride injection.

- (a) Specifications. The drug is a sterile aqueous solution. Each milliliter contains 50 milligrams of ethylisobutrazine hydrochloride.
- (b) *Sponsor*. See No. 000061 in §510.600(c) of this chapter.
- (c) Conditions of use. (1) It is used in dogs as a tranquilizer.¹
- (2) It is administered intramuscularly at a dosage level of 2 to 5 milligrams of ethylisobutrazine hydrochloride per pound of body weight for profound tranquilization. It is administered intravenously at a dosage level of 1 to 2 milligrams of ethylisobutrazine hydrochloride per pound of body weight to effect.¹
- (3) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.¹
- (4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.870 Etodolac.

- (a) Specifications. Each milliliter contains 100 milligrams (mg) etodolac.
- (b) Sponsor. See No. 000010 in §510.600 of this chapter.
- (c) Conditions of use in dogs—(1) Amount. Administer 4.5 to 6.8 mg/pound (10 to 15 mg/kilogram) body weight as a single, dorsoscapular subcutaneous injection. If needed, the daily dose of etodolac tablets as in \$520.870 of this chapter may be given 24 hours after the injection.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information